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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,156	03/02/2000	Rick L Tarleton	235.00200101	4178

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EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,156	TARLETON ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) *1-39 and 70-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/4/2000*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed December 18, 2003 has been received and entered. Consequently claims 1-73 are pending in the instant application, of which claims 1-39 and 70-73 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Objections

1. The objection of claims 40 and 62-64 for depending upon a non-elected claim is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claims 40-69 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic immunization comprising a vector which encodes TSA-1, does not reasonably provide enablement for a therapeutic immunization with any polypeptide derived from a protozoan is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants are asserting that the specification offers guidance (page 13 & 14) as to which polypeptides to select in order to identify polypeptides that would be likely to generate an immune response that is broader than just an antigenic response. Applicants further assert that the specification details methods (Examples I & II) that the

researcher can use to evaluate, without undue experimentation, the immunogenic response in a mouse model generated by the candidate surface-associated or secreted polypeptide.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

First, as set forth by Plotkin et al "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen." This teaching directly addresses factors 1, 4, 5, 6, 7 and 8.

Second, Applicants sole working example is that of the antigen TSA-1. Enablement for this particular antigen has not been questioned. However, Applicants claims (any protozoan polypeptide associated with a protozoan cell surface or secreted by a protozoan) are simply not

commensurate in scope with Applicants teachings. This directly affects Factors 1, 2, 3, 4 and 8.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Finally, Applicants assert that the specification details methods (Examples I & II) that the researcher can use to evaluate, without undue experimentation, the immunogenic response in a mouse model generated by the candidate surface-associated or secreted polypeptide. However, Applicants are directed to their own claim language of a multicomponent "vaccine." A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Again, considering the Wands analysis, Applicants specification has not provided guidance as to which of the multitude of protozoan polypeptides "associated with the cell surface or secreted" are capable of eliciting this immunoprotective response. Applicants specification offers a mere statement that a multitude of proteins are part of the invention but does not offer guidance beyond the antigen TSA-1.

For reasons of record, as well as those set forth above this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 61-64 rejected under 35 U.S.C. 102(a) as being anticipated by Wizel et al is maintained.

Applicants are asserting that Wizel et al do not report the actual preparation or use of a multicomponent polypeptide or polynucleotide vaccine.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the disclosure of Wizel et al. Wizel et al disclose of injecting intramuscularly VR1012 TSA1.7 (an expression vector comprising a polynucleotide sequence which encodes an immunogenic polypeptide) suspended in 50 μl of PBS. (See page 5074). Applicants claims recite a "multicomponent vaccine." However each and every limitation has been addressed. There is no claim limitation to exclude a multicomponent to include the DNA

sequence as one component and a carrier as another component. Accordingly the disclosure of Wizel et al is deemed to be a multicomponent vaccine.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claims 61-64 rejected under 35 U.S.C. 102(a) as being anticipated by Costa et al is maintained.

Applicants are asserting that Costa et al teach only a single component vaccine.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the disclosure of Costa et al. Costa et al disclose of injecting intramuscularly Cardiotoxin and plasmid DNA. Applicants claims recite a "multicomponent vaccine." However each and every limitation has been addressed. There is no claim limitation to exclude a multicomponent to include the DNA sequence as one component and an adjuvant such as Cardiotoxin as another component. Accordingly the disclosure of Costa et al is deemed to be a multicomponent vaccine.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

5. The rejection of claims 61-64 rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al is maintained.

Applicants are asserting that Reed et al do not teach of a multicomponent vaccine.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the disclosure of Reed et al. Reed et al disclose of administering an immunogenic polypeptide suspended in Freund's adjuvant. Applicants claims recite a "multicomponent vaccine." However each and every limitation has been addressed. There is no claim limitation to exclude a multicomponent to include the immunogenic polypeptide as one component and an adjuvant as another component. Accordingly the disclosure of Reed et al is deemed to be a multicomponent vaccine.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

The following new grounds of rejection are applied to the amended claims:

Claim Rejections - 35 USC § 112

6. Claims 40-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "associated with a protozoan cell surface." One of skill in the art would be unable to determine the metes

and bounds of the claimed invention. For instance, does associated include molecules bound to the surface, enzymes that acted on the protein destined for the surface, molecules which bind to the surface expressed molecule, and what kind of binding, (eg covalent, hydrophobic, Van der Waals, etc.)? One of skill in the art would simply be unable to determine if the patent was being infringed for lack of a clearly identifiable class of compounds which are "associated with a protozoan cell surface."

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
April 2, 2004